

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 1 of 39	

INSTRUCTIONS FOR USE

MITRACLIP SYSTEM
Steerable Guide Catheter Ref No. SGC01ST
Clip Delivery System Ref No. CDS02ST

MITRACLIP SYSTEM ACCESSORIES
Stabilizer Ref No. SZR01ST
Lift Ref No. LFT01ST
Support Plate Ref No. PLT01ST

WARNING: Read all instructions carefully. Failure to follow these instructions, warnings and precautions may lead to device damage or patient injury. Use of the MitraClip System should be restricted to those physicians trained to perform invasive endovascular and transseptal procedures and to those physicians trained in the proper use of the system.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 2 of 39	

TABLE OF CONTENTS

INTENDED USE	Error! Bookmark not defined.
POTENTIAL COMPLICATIONS AND ADVERSE EVENTS	3
PATIENT COUNSELING.....	4
HOW SUPPLIED	5
STORAGE	5
MITRACLIP SYSTEM DIMENSIONS.....	6
GLOSSARY OF ACRONYMS	7
DEVICE DESCRIPTION.....	8
MITRACLIP SYSTEM ACCESSORIES OVERVIEW	9
REQUIRED ACCESSORIES.....	12
ADDITIONAL REQUIRED EQUIPMENT NOT INCLUDED	12
MITRACLIP PROCEDURE STEP-BY-STEP INSTRUCTIONS	13
1.0 DEFINITION OF TERMS.....	19
2.0 PATIENT PREPARATION.....	21
3.0 MITRACLIP SYSTEM PREPARATION BEFORE USE	21
4.0 ACCESS TO THE MITRAL VALVE	27
5.0 STEERABLE GUIDE CATHETER INSERTION.....	27
6.0 CLIP DELIVERY SYSTEM INSERTION	28
7.0 INITIAL MITRACLIP SYSTEM POSITIONING IN THE LEFT ATRIUM	29
8.0 FINAL MITRACLIP SYSTEM POSITIONING.....	30
9.0 GRASPING THE LEAFLETS AND VERIFYING THE GRASP	30
10.0 CLOSING THE CLIP AND EVALUATING CLIP POSITION	31
11.0 MITRACLIP DEVICE PRE-DEPLOYMENT CLIP ASSESSMENT.....	32
12.0 CLIP DEPLOYMENT	33
13.0 ADDITIONAL MITRACLIP DEVICE PLACEMENT	35
14.0 MITRACLIP SYSTEM REMOVAL	35
PATENTS	39
NON-HARMONIZED SYMBOLS USED FOR LABELING	39

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 3 of 39	

INDICATION FOR USE

The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR \geq 3+) in patients who have been determined by a cardiac surgeon to be too high risk for open mitral valve surgery and in whom existing co-morbidities would not preclude the expected benefit from correction of the mitral regurgitation.

WARNINGS

The MitraClip Device should be implanted with sterile techniques using fluoroscopy and echocardiography (e.g trans-esophageal [TEE] and trans-thoracic [TTE]) in a facility with on-site cardiac surgery and immediate access to a cardiac operating room.

Read all instructions carefully. Failure to follow these instructions, warning and precautions may lead to device damage, user injury or patient injury. Use universal precautions for biohazards and sharps while handling the MitraClip System to avoid user injury.

Use of the MitraClip should be restricted to those physicians trained to perform invasive endovascular and transseptal procedures and those trained in the proper use of the system.

The Clip Delivery System is designed for single use only. Cleaning, re-sterilization and/or reuse may result in infections, malfunction of the device or other serious injury or death.

PRECAUTIONS

Note the "Use by" date specified on the package.

Inspect all product prior to use. DO NOT use if the package is opened or damaged.

SPECIAL PATIENT POPULATIONS

Pregnancy

The MitraClip device has not been tested in pregnant women. Effects on the developing fetus have not been studied. While there is no contraindication, the risks and reproductive effects are unknown at this time.

Gender

No safety or effectiveness related gender differences were observed in clinical studies.

Ethnicity

Insufficient subject numbers prevent ethnicity-related analyses on the clinical safety and effectiveness.

Pediatrics

Safety and effectiveness of the MitraClip device has not been established in pediatric patients.

Anatomic Considerations

The following anatomic considerations may interfere with placement of the MitraClip Device or mitral valve leaflet insertion. Examples of such conditions for which the safety and effectiveness of the MitraClip has not been established include the following:

- Primary regurgitant jet outside the A2-P2 area
- Mitral valve orifice area < 4.0cm²

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 4 of 39	

- Flail width \geq 15mm
- Flail gap \geq 10mm
- Coaptation length $<$ 2mm

POTENTIAL COMPLICATIONS AND ADVERSE EVENTS

The following ANTICIPATED EVENTS have been identified as possible complications of the MitraClip procedure.

Allergic reaction (anesthetic, contrast, Heparin, nickel alloy, latex) Aneurysm or pseudo-aneurysm Arrhythmias Atrial fibrillation Atrial septal defect requiring intervention Arterio-venous fistula Bleeding Cardiac arrest Cardiac perforation Cardiac tamponade/Pericardial Effusion MitraClip erosion, migration or malposition MitraClip Device thrombosis MitraClip System component(s) embolization Coagulopathy Conversion to standard valve surgery Death Deep venous thrombus (DVT) Dislodgement of previously implanted devices Drug reaction to anti-platelet/anticoagulation agents/contrast media Dyspnea Edema Emboli (air, thrombus, MitraClip Device) Emergency cardiac surgery Endocarditis Esophageal irritation Esophageal perforation or stricture Failure to deliver MitraClip to the intended site Failure to retrieve MitraClip System components Fever or hyperthermia Gastrointestinal bleeding or infarct	Hematoma Hemolysis Hemorrhage requiring transfusion Hypotension/hypertension Infection and pain at insertion site Infection and pain at incision site Lymphatic complications Mesenteric ischemia Mitral stenosis Mitral valve injury Multi-system organ failure Myocardial infarction Nausea/vomiting Peripheral ischemia Prolonged angina Prolonged ventilation Pulmonary congestion Pulmonary thrombo-embolism Renal insufficiency or failure Respiratory failure/atelectasis/pneumonia Septicemia Single leaflet device attachment (SLDA) Skin injury or tissue changes due to exposure to ionizing radiation Stroke or transient ischemic attack (TIA) Urinary tract infection Vascular trauma, dissection or occlusion Vessel spasm Vessel perforation or laceration Worsening heart failure Worsening mitral regurgitation Wound dehiscence
--	--

PATIENT COUNSELING

Patients undergoing any procedures known to potentially be associated with bacteremia after implantation of the MitraClip Device should be prescribed prophylactic antibiotic therapy prior to such procedures.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 5 of 39	

Short-term anticoagulation therapy may be necessary after mitral valve repair with the MitraClip Device. Prescribe anticoagulation and other medical therapy per institutional guidelines.

After placement of a MitraClip Device, the Implant Identification Card should be filled out and the patient should be instructed to carry it at all times.

All patients should be advised to limit strenuous physical activity for at least the first month post-procedure or longer if warranted.

Physicians should consider the following in counseling patients about the MitraClip Device:

- Discuss the risks associated with MitraClip Device placement.
- Discuss the risk/benefit considerations for the patient.

HOW SUPPLIED

Contents:

CDS02ST: One (1) MitraClip Device, one (1) Clip Delivery System, one (1) MitraClip Device Implant Card, one (1) Instructions for Use.

Sterile:

For the Clip Delivery System and Steerable Guide Catheter only: these devices are provided sterile, in a thermoformed tray with lid, in sealed pouches. Parts of the devices that are in either direct or indirect contact with circulating blood are non-pyrogenic. Confirm the "Use by" date specified on the package. DO NOT use the MitraClip System if the "Use by" date has passed. These devices are intended for single use only. DO NOT re-sterilize. DO NOT use if the package is opened or damaged. Cleaning, re-sterilization and/or re-use may result in infections, malfunction of the device and other serious injury or death.

The white Guide tip shape retainer and transparent protective tubing are provided sterile and pre-installed on the distal tip of the Steerable Guide Catheter. The Fasteners and the Silicone Pad used with the Stabilizer are provided sterile with the Steerable Guide Catheter. The Dilator, Fasteners and the Silicone Pad are intended for single use only. DO NOT re-sterilize. Cleaning, re-sterilization and/or re-use may result in infections, malfunction of the device and other serious injury or death.

Non-sterile:

The Stabilizer, Support Plate and Lift are provided non-sterile. Follow the cleaning and sterilization instructions provided with the Stabilizer, Support Plate and Lift.

STORAGE

Handle with care. Store in original packaging. Keep dry. Keep away from sunlight.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 6 of 39	

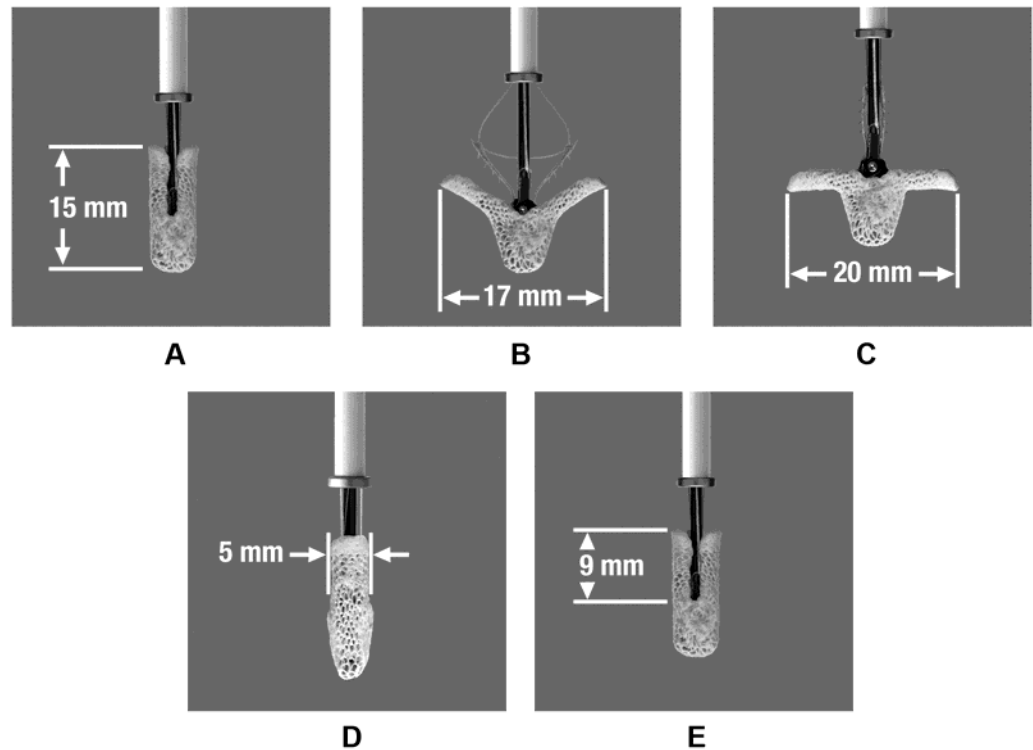
MITRACLIP SYSTEM DIMENSIONS

Component	Dimension
<i>Delivery Catheter</i>	
Extended Length (from Sleeve curved at 90 degrees)	45 mm – 70 mm
Catheter Shaft Outer Diameter	3.4 mm (10 Fr)
<i>Steerable Sleeve</i>	
Working Length	1095 mm
Catheter Distal Shaft Outer Diameter	5.3 mm (16 Fr)
<i>MitraClip Device</i>	
Closed Clip Length (Figure 1A)	15 mm maximum
Grasping Width at 120 degrees (Figure 1B)	17 mm minimum
Clip Width at 180 degrees (Figure 1C)	20 mm maximum
Arm Width (Figure 1D)	5 mm maximum
Arm Length (Coaptation Length) (Figure 1E)	9 mm maximum
<i>Steerable Guide Catheter</i>	
Working Length	800 mm
Catheter Shaft Inner Diameter	5.5 mm (16 Fr)
Catheter Shaft Outer Diameter	8.1 mm (24 Fr)
Catheter Distal Tip Diameter	7.7 mm (23 Fr)
Catheter Septal Crossing Diameter	7.4 mm (22 Fr)
<i>Dilator</i>	
Working Length	1220 mm
Shaft Inner Diameter	1.0 mm (3 Fr)
Shaft Outer Diameter	5.4 mm (16 Fr)
Distal Tip Outer Diameter	1.5 mm (4 Fr)

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

Figure 1: MitraClip Device Dimensions



GLOSSARY OF ACRONYMS

Guide:	Steerable Guide Catheter	RA:	Right Atrium
CDS:	Clip Delivery System	LA:	Left Atrium
Sleeve:	Steerable Sleeve	LV:	Left Ventricle
DC:	Delivery Catheter	RO:	Radiopaque
Clip:	MitraClip Device (Implant)	MR:	Mitral Regurgitation

CONFIDENTIAL

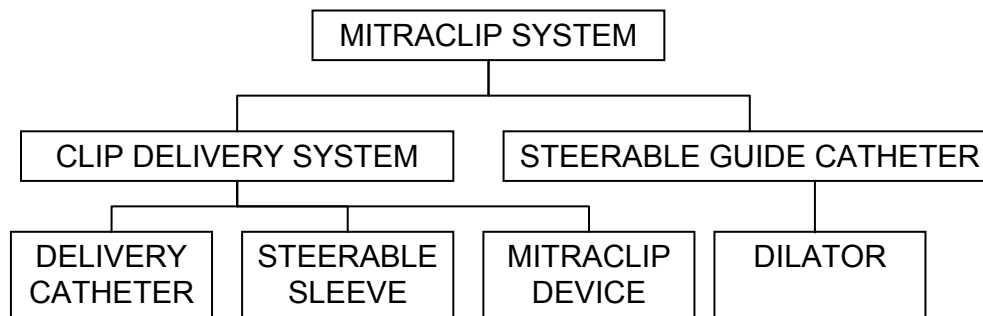
May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 8 of 39	

DEVICE DESCRIPTION

The MitraClip System consists of two parts: 1) the Clip Delivery System and 2) the Steerable Guide Catheter.

The Clip Delivery System consists of three major components: 1) the Delivery Catheter 2) the Steerable Sleeve and 3) the MitraClip Device. The Clip Delivery System is introduced into the body through a Steerable Guide Catheter which includes a dilator. The Clip Delivery System and Steerable Guide Catheter constitute the MitraClip System.



The Clip Delivery System (Figures 2 and 4) is used to advance and manipulate the implantable MitraClip Device for proper positioning and placement on the mitral valve leaflets. The Clip Delivery System is designed to deploy the implant in a way that requires multiple steps to ensure safe delivery of the device.

The outer surfaces of the Delivery Catheter and the Steerable Guide Catheter have a hydrophilic coating.

The MitraClip Device (Figure 6) is a percutaneously implanted mechanical Clip. The MitraClip Device grasps and coapts the mitral valve leaflets resulting in fixed approximation of the mitral leaflets throughout the cardiac cycle. The MitraClip Device is placed without the need for arresting the heart or cardiopulmonary bypass. The implantable MitraClip Device is manufactured with metal alloys and polyester fabric (Clip cover) that are commonly used in cardiovascular implants.

The MitraClip Device arms can be adjusted to any position from fully opened, fully inverted and fully closed. These positions are designed to allow the MitraClip Device to grasp and approximate the leaflets of the mitral valve using controls on the Delivery Catheter Handle. The MitraClip Device can be locked, unlocked and repeatedly opened and closed. The Grippers can be raised or lowered repeatedly.

The MitraClip Device is magnetic resonance conditional. It is considered safe for patients undergoing magnetic resonance imaging procedures with:

- Static magnetic field up to 3 Tesla;
- Maximum spatial gradient in static field of 2500 gauss/cm or less;
- Maximum whole-body averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of scanning.



CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 9 of 39	

Magnetic resonance image quality may be compromised if the area of interest is in the exact same area, or relatively close to the MitraClip Device. A maximum image artifact of 60 x 70 mm was measured in testing conducted in a 3T magnetic resonance system. It may be necessary to optimize the magnetic resonance imaging parameters due to the presence of the implant.

The MitraClip Device can be removed using standard surgical techniques (and/or according to applicable study protocols) and can be disposed of according to institutional guidelines (and/or applicable study protocols).

The Steerable Guide Catheter (Figure 3a) is used to introduce the Clip Delivery System into the left side of the heart through the interatrial septum. The Steerable Guide Catheter is also used to position and orient the Clip Delivery System to the appropriate location above the mitral valve. The Dilator (Figure 3b) is used for the introduction of the Steerable Guide Catheter into the femoral vein and left atrium.

MITRACLIP SYSTEM ACCESSORIES OVERVIEW

Several accessories are used in conjunction with the MitraClip System including: 1) a Stabilizer, 2) a Lift 3) a Support Plate, 4) a Silicone Pad and 5) Fasteners. The Stabilizer is provided separately as a non-sterile reusable device and must be cleaned and sterilized prior to each use. The Stabilizer is used on the sterile field to support and position the Steerable Guide Catheter and Clip Delivery System during the procedure. The Lift and Support Plate are provided separately as non-sterile reusable devices and must be cleaned prior to each use. The Lift and Support Plate are used outside the sterile field to provide a stable platform for the Stabilizer and MitraClip System during the procedure. Follow the cleaning and sterilization instructions provided with the Stabilizer, Support Plate and Lift. The Silicone Pad and Fasteners are single use accessories and are provided sterile with the Steerable Guide Catheter packaging. The Silicone Pad is used on the sterile field under the Stabilizer to prevent incidental movement of the Stabilizer during the procedure. The Fasteners are used on the sterile field to secure the Steerable Guide Catheter and Clip Delivery System to the Stabilizer.

Legend of Figure Labels (See page 11)

Figure 2: Clip Delivery System (CDS) 1 Delivery Catheter Handle 2 Delivery Catheter Fastener 3 A/P Knob 4 M/L Knob 5 Steerable Sleeve Handle 6 Clip Introducer 7 MitraClip Device Figure 3a: Steerable Guide Catheter 8 Hemostasis Valve 9 Alignment Marker 10 Flush Port 11 +/- Knob 12 Proximal Shaft 13 Distal Shaft 14 Radiopaque Tip Ring	Figure 4: CDS Handles 18 Actuator Knob 19 Release Pin 20 Arm Positioner 21 Lock Lever Cap 22 Gripper Lever Cap 23 Lock Lever 24 Gripper Lever 25 Delivery Catheter Top Flush Port (Bottom Flush Port Not Shown) 26 Delivery Catheter Handle 27 Delivery Catheter Fastener 28 Sleeve Flush Port 29 A/P Knob 30 M/L Knob 31 Steerable Sleeve Handle Figure 5: CDS Distal End	36 Sleeve Radiopaque Tip Ring 37 Delivery Catheter Shaft 38 Delivery Catheter Radiopaque Ring 39 MitraClip Device Figure 6: MitraClip Device Positions A Clip fully closed (low profile) B Clip opened to 180 degrees C Clip closed to 120 degrees D Clip closed to 60 degrees E Clip closed to 20 degrees F Clip inverted G Clip fully inverted
---	---	--

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 10 of 39	

Figure 3b: Dilator 15 Rotating Hemostatic Valve 16 Flush Port 17 Echogenic Spiral Groove	32 Longitudinal Alignment Marker 33 Key 34 Steerable Sleeve Shaft 35 Radiopaque Alignment Markers 35a Proximal 35b Distal	
--	--	--

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

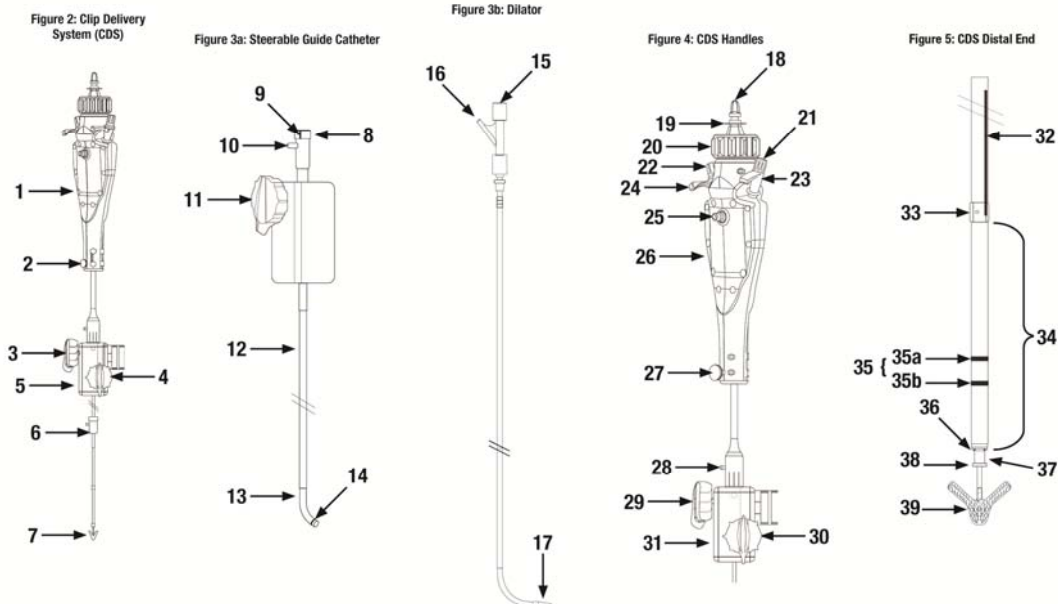
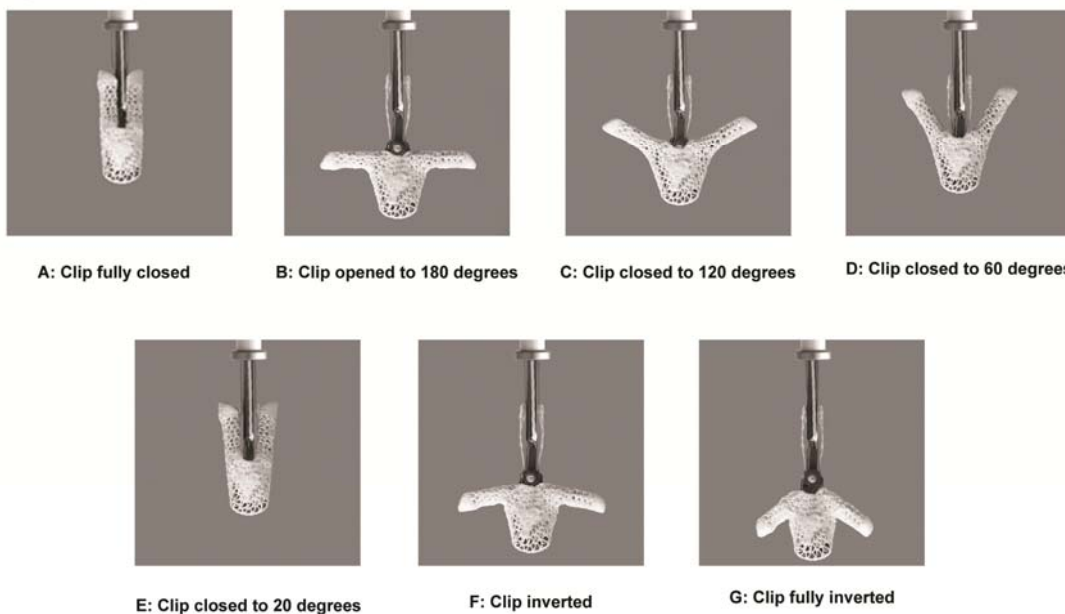


Figure 6: MitraClip Device Positions



CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 12 of 39	

The Steerable Guide Catheter and Clip Delivery System (Steerable Sleeve, Delivery Catheter and Clip) are steered and actuated by the use of control knobs, levers and fasteners located on the handles.

Table 1: MitraClip System Handle Controls

Device	Control	Function
Steerable Guide Catheter	+/- Knob	Tip deflection
Steerable Sleeve	M/L Knob	Tip deflection
	A/P Knob	Tip deflection
Delivery Catheter	Lock Lever	Locks-Unlocks Clip via Lock Line
	Gripper Lever	Raises-Lowers Grippers via Gripper Line
	Arm Positioner	Opens-Closes Clip Arms
	DC Fastener	Locks-Unlocks DC translation/torque
	Lock Lever Cap	Controls removal of Lock Line
	Gripper Lever Cap	Controls removal of Gripper Line
	Release Pin	Prevents Actuator Knob turning
	Actuator Knob	Turns actuator shaft for Clip deployment

REQUIRED ACCESSORIES

SZR01ST: One (1) Stabilizer.

LFT01ST: One (1) Lift.

PLT01ST: One (1) Support Plate.

One (1) Silicone Pad, three (3) Fasteners (All are included sterile with the Steerable Guide Catheter).

ADDITIONAL REQUIRED EQUIPMENT NOT INCLUDED

Transseptal sheath and guidewire.

Transseptal needle.

Step-up dilators.

260 cm 0.035" super stiff exchange length guidewire.

High pressure three way stopcocks (5).

Arterial high pressure extension tubing (3).

50-60 cc syringes with luer fitting (2).

1000 ml pressure bags (2).

Sterile IV tubing with thumbwheel occluders (2).

Heparinized sterile saline solution (2, 1 liter bags).

Rolling IV Pole.

Sterile Basin.

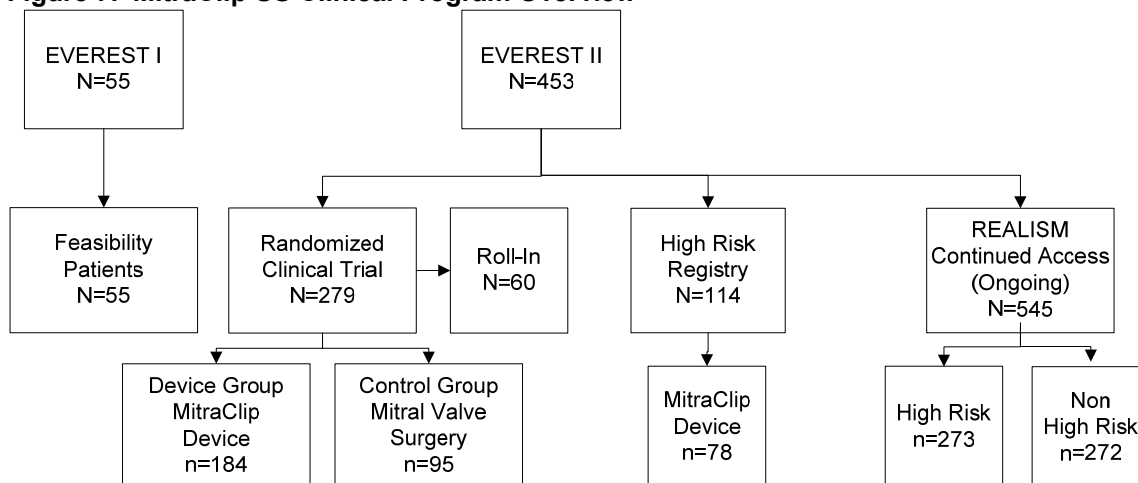
CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

OVERVIEW OF CLINICAL STUDIES

Figure 7 presents an overview of the MitraClip clinical program in the United States.

Figure 7. MitraClip US Clinical Program Overview



EVEREST I Trial (Feasibility)

The EVEREST I trial was a prospective, multi-center, registry trial designed to evaluate the preliminary safety and effectiveness of the MitraClip device in the treatment of moderate-to-severe (3+) or severe (4+) chronic MR using up to 2 MitraClip devices per patient. The EVEREST I trial demonstrated the preliminary safety and feasibility of the MitraClip device as a percutaneous method for the reduction of MR severity. EVEREST I enrolled 55 patients at 12 US sites. Enrolled patients were required to complete clinical follow up at 30 days, 6, 18 and 24 months, and 3, 4, and 5 years. The primary safety endpoint of EVEREST I was MAE rate through 30 days (acute safety). Multiple additional secondary endpoints were pre-specified for safety and effectiveness for reporting with descriptive statistics.

The study is now closed.

EVEREST II Randomized Clinical Trial (RCT)

The EVEREST II RCT was a landmark trial, being the first randomized trial to compare a percutaneous intervention for the reduction of MR to standard of care mitral valve surgery. The RCT was a prospective, randomized (2:1; MitraClip device: Surgery Control) active controlled, multi-center, clinical trial designed to evaluate the safety and effectiveness of the MitraClip device in the treatment of moderate-to-severe (3+) or severe (4+) chronic MR using up to 2 MitraClip devices per patient. The EVEREST II RCT was designed to demonstrate superiority of safety and non-inferiority of effectiveness of the MitraClip device compared to mitral valve repair or replacement surgery. Both primary safety and effectiveness endpoints were pre-specified along with multiple secondary endpoints. The RCT studied the treatment of MR with serial echocardiographic follow-up and independent echocardiographic core laboratory assessment of MR and left ventricular outcomes. The RCT study enrolled 279 patients at 37 North American sites. Enrolled patients were required to complete clinical follow up at 30 days, 6, 18 and 24 months, and 3, 4, and 5 years. The primary safety endpoint in the RCT was the proportion of per protocol patients with major adverse events (MAEs) at 30 days. MAEs were defined to include significant adverse clinical events. The primary effectiveness endpoint was the proportion of Per

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 14 of 39	

Protocol patients who met Clinical Success, defined as freedom from death, surgery for valve dysfunction or MR $\geq 2+$ at 12 months. Both the primary safety and effectiveness endpoints were also analyzed on an Intention to Treat basis. Pre-specified analyses for additional secondary safety and effectiveness endpoints included: mitral valve repair success, quantitative echo measures of left ventricular function, MR severity rating, afterload reducing medications, life-table estimates of durability and Bayesian durability at 24 months. Multiple additional secondary endpoints were pre-specified for safety and effectiveness for reporting with descriptive statistics. Follow up through 3 years is currently available for all patients, and yearly follow-up through 5 years is ongoing. Results of this study showed that the safety advantages of the percutaneous procedure were offset by the diminution of MR reduction with MitraClip compared to surgery, and therefore good surgical candidates should continue to receive surgical intervention.

EVEREST II High Risk Registry

The EVEREST II High Risk registry (HRR) I was a prospective, multi-center, registry designed to evaluate the safety and effectiveness of the MitraClip device in the treatment of high surgical risk ($\geq 12\%$) patients with moderate-to-severe (3+) or severe (4+) chronic MR using up to 2 MitraClip devices per patient. HRR enrolled 78 patients at 35 North American sites. Enrolled patients were required to complete clinical follow up at 30 days, 6, 18 and 24 months, and 3, 4, and 5 years. The primary safety endpoint of the HRR was procedural mortality at 30 days or prior to discharge, whichever is longer. The observed procedural mortality was compared with the predicted procedural mortality of the same patients. The major effectiveness endpoints were: freedom from death at 12 months, freedom from death and MR $> 2+$ at 12 months, NYHA Functional Class, QOL as measured by SF36, LV function, and re-hospitalizations for CHF at 12 months. Multiple additional secondary endpoints were pre-specified for safety and effectiveness for reporting with descriptive statistics. Follow up through 3 years is currently available for all patients, and yearly follow up through 5 years is ongoing.

EVEREST II REALISM Continued Access Study

This information will be updated and included at the time of the final labeling.

Table 2 summarizes the clinical trial designs for the EVEREST I Feasibility Study, the EVEREST II RCT, the EVEREST II HRR, and supporting REALISM HR continued access registry.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 15 of 39	

Table 2: Clinical Trial Designs

	EVEREST I Feasibility	EVEREST II Randomized	EVEREST II High Risk Registry	EVEREST II Continued Access Registry (REALISM) High Risk
Study Type	Multi-center Single-arm Registry Open-label	Multi-center Randomized (2:1) MitraClip: Surgery control	Multi-center Single-arm Registry	Multi-center Single-arm Registry
Number of Subjects Enrolled	Total : 55	Total: 279 Device: 184 Control: 95	78	Total: 273
Number of Device Implants Allowed	First 10: 1 Last 45: 2	2	2	2
Post Procedure Antiplatelet Therapy	Aspirin 1 year 6 months Clopidogrel Plavix 30 days	Aspirin 6 months Clopidogrel 30 days	Aspirin 6 months Clopidogrel 30 days	Aspirin 6 months
Primary Safety Endpoint	MAE 30 days	MAE 30 days	Procedural mortality (30 days)	MAE 30 days and 12 months
Primary Effectiveness Endpoint	NA	Freedom from death, mitral valve surgery, MR > 2+ at 12 months	Freedom from death and MR > 2+ at 12 months	Freedom from death, mitral valve surgery, MR > 2+ at 12 months
Major Secondary Safety Endpoints	MAE 12 months Vascular/bleeding Endocarditis Hemolysis ASD Mitral Stenosis	MAE 12 months Vascular/bleeding Endocarditis Hemolysis ASD Mitral Stenosis	MAE 12 months Vascular/bleed Endocarditis Hemolysis ASD Mitral Stenosis	MAE 12 months Vascular/bleeding Endocarditis Hemolysis ASD Mitral Stenosis
Major Secondary Effectiveness Endpoints	NYHA, QOL LV function	MV repair LV function NYHA, QOL 2 year durability	NYHA, QOL LV function, re-hospitalization for CHF at 12 m	NYHA, QOL LV function
Clinical Follow-up Visits	30 days, 6, 12, 18, 24 months, 3, 4, 5 years	30 days, 6, 12, 18, 24 months, 3, 4, 5 years	30 days, 6, 12, 18, 24 months, 3, 4, 5 years	30 days, 6, 12, 24 months, 3, 4, 5 years
Echo Follow-up (TTE)	Discharge and all clinical follow-up visits	Discharge and all clinical follow-up visits	Discharge and all clinical follow-up visits	Discharge and all clinical follow-up visits

Principal evidence of safety and effectiveness of the MitraClip Device for the indicated use is derived from three hundred fifty one (351) patients too high risk for mitral valve surgery that have completed 1 year of follow-up after treatment with the MitraClip Device and comprise the Integrated High Surgical Risk Cohort (Integrated HSR Cohort). The Integrated HSR Cohort is a pooled cohort including 78 patients enrolled in the EVEREST II HRR and 273 patients enrolled under similar eligibility criteria in the high risk arm of the REALISM Continued Access study. These studies evaluated performance of the MitraClip device in symptomatic patients too high risk for surgery with moderate-to-severe (3+) or severe (4+) chronic mitral regurgitation (MR).

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 16 of 39	

CLINICAL RESULTS IN PATIENTS TOO HIGH RISK FOR MITRAL VALVE SURGERY

A summary of the results of the Integrated High Surgical Risk Cohort is provided below:

Table 3: Integrated HSR Cohort – Baseline and Demographic Characteristics

Characteristic	Integrated HSR Cohort (N = 351)
Age (years) Mean \pm SD (N)	75.7 \pm 10.5 (351)
Patients over 75 years of age	58.1% (204/351)
Female Gender	39.0% (137/351)
Coronary Artery Disease	82.2% (287/349)
Prior Myocardial Infarction	50.7% (177/349)
Atrial Fibrillation History	68.5% (217/317)
Prior Stroke	12.8% (45/351)
Diabetes	39.4% (138/350)
Moderate to Severe Renal Disease	30.5% (107/351)
Chronic Obstructive Pulmonary Disease (w/ or w/o Home O2)	28.9% (101/350)
Hypertension	89.5% (314/351)
Previous Cardiovascular Surgery	59.8% (210/351)
Previous Percutaneous Coronary Intervention	49.9% (175/351)
NYHA Class III/IV Heart Failure	84.9% (298/351)
Functional MR Etiology	70.1% (246/351)
LV Ejection Fraction (%) Mean \pm SD (N)	47.5 \pm 14.2 (318)
LV Internal Diameter systole (cm) Mean \pm SD (N)	4.4 \pm 1.1 (323)

Table 4: Integrated High Surgical Risk Cohort Safety and Effectiveness

Safety	Procedural Mortality 30-Day or Hospital Discharge (whichever is longer)	4.8%
	Freedom from Death at 12 months	77.2%
Effectiveness	Freedom from Death and MR > 2+ at 12 months	62.6%

* Integrated High Surgical Risk Cohort was derived by combining 78 EVEREST II HRR patients with 273 REALISM HR patients who were enrolled between January 2009 and March 2011.

Table 5: High Surgical Risk Cohort Mortality Comparison to Patients Managed Medically

	MitraClip* (N = 211)	Duke (N = 211)
30-Day Freedom from Mortality	94.7%	91.9%
12-Month Freedom from Mortality	75.9%	68.8%

* Mitraclip Cohort was derived by combining 78 EVEREST II HRR patients with 133 REALISM HR patients who were enrolled between January 2009 and February 2010 and compared to similar demographic high surgical risk patients treated with medical management at Duke University Medical Center between 2000 and 2010.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

Table 6: Integrated High Surgical Risk Cohort MAE at 30 Days and 12 Months

Description of Event	% Patients (n/N)	
	30-Day	12-Month
Death	4.8% (17/351)	22.8% (80/351)
Myocardial infarction	1.1% (4/351)	2.3% (8/351)
Re-operation for failed surgical repair or replacement	0.0% (0/351)	0.0% (0/351)
Non-elective cardiovascular surgery for adverse events	0.3% (1/351)	0.3% (1/351)
Stroke	2.6% (9/351)	3.4% (12/351)
Renal Failure	1.7% (6/351)	5.4% (19/351)
Deep wound infection	0.0% (0/351)	0.0% (0/351)
Ventilation > 48 hours	2.8% (10/351)	5.4% (19/351)
GI complication requiring surgery	0.3% (1/351)	1.4% (5/351)
New onset of permanent AF	0.3% (1/351)	0.3% (1/351)
Septicemia	0.9% (3/351)	4.3% (15/351)
Transfusion ≥ 2 units	13.4% (47/351)	22.5% (79/351)
Total^a	18.8% (66/351)	37.6% (132/351)
Total^a (Excluding Transfusions ≥ 2 units)	9.1% (32/351)	27.9% (98/351)

^a Total number of patients may not equal the sum of patients in each row since one patient may experience multiple events.

Table 7: Integrated High Surgical Risk Cohort Other Secondary Safety Events at 30 Days and 12 Months

Description of Event	% Patients (n/N)	
	30-Day	1-Year
Major Bleeding Complication	9.7% (34/351)	11.7% (41/351)
Major Vascular Complication	3.4% (12/351)	4.0% (14/351)
Non-Cerebral Thromboembolism	0.3% (1/351)	0.6% (2/351)
Endocarditis	0.0% (0/351)	0.3% (1/351)
Thrombosis	0.0% (0/351)	0.0% (0/351)
Hemolysis	0.0% (0/351)	0.0% (0/351)
Atrial Septal Defect requiring intervention	1.7% (6/351)	3.1% (11/351)
Persistent Atrial Fibrillation, New Onset	2.6% (9/351)	6.8% (24/351)
Heart Block/Other arrhythmia requiring permanent pacemaker	1.1% (4/351)	2.6% (9/351)

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 18 of 39	

Table 8: Integrated High Surgical Risk Cohort LV Measurements, Surviving Patients with Paired Data at Baseline and 12 Months

LV Measurement	N	Baseline	12-Month	Difference (12-Month - Baseline)	p-value
LVEDV, ml					
Mean ± SD	203	160.5 ± 55.9	142.6 ± 53.1	-17.9 ± 31.8	<0.001
LVIDd, cm					
Mean ± SD	221	5.6 ± 0.8	5.4 ± 0.8	-0.2 ± 0.4	<0.001
LVESV, ml					
Mean ± SD	202	87.0 ± 46.8	78.9 ± 43.9	-8.1 ± 23.2	<0.001
LVIDs cm					
Mean ± SD	210	4.3 ± 1.1	4.1 ± 1.1	-0.1 ± 0.6	0.002

Table 9: Integrated High Surgical Risk Cohort NYHA Class and SF-36 Quality of Life, Surviving Patients with Paired Data at Baseline and 12 Months

Endpoint	Baseline	12 Months
NYHA Functional Class III/IV % (n/N)	82.1% (192/234)	17.1% (40/234)
Quality of Life, Physical Component Summary Score Mean ± SD (N)	34.0±9.1 (191)	38.8±11.3 (191)
Quality of Life, Mental Component Summary Score Mean ± SD (N)	44.9±13.5 (191)	49.8±12.2 (191)

Table 10: Integrated High Surgical Risk Cohort Heart Failure Hospitalizations

	12-Month Pre-enrollment	Post-discharge through 12-Month	p-value
# Patients	149	67	
# Events	277	118	
Rate per patient-year of follow-up ^a (95% Two-sided Conf Int)	0.79 (0.70, 0.89)	0.41 (0.34, 0.49)	< 0.0001

^a p-value and confidence interval are obtained from a Poisson regression model

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 19 of 39	

MITRACLIP PROCEDURE STEP-BY-STEP INSTRUCTIONS

1.0 DEFINITION OF TERMS

Defined Terms are in italics throughout document.

TERM	DEFINITION AND RELATED TECHNIQUE
<i>Lock the Clip</i>	<ol style="list-style-type: none"> 1. Rotate the Lock Lever outward. 2. Fully advance the Lock Lever. 3. Rotate the Lock Lever inward to engage the lever.
<i>Unlock the Clip and Open the Clip Arms</i>	<ol style="list-style-type: none"> 1. Rotate the Lock Lever outward and then retract the lever until the mark on the lever is fully exposed. 2. Rotate the Lock Lever inward to engage the lever. 3. Turn the Arm Positioner at least 1/2 turn in the “Close” (clockwise) direction. 4. Turn the Arm Positioner in the “Open” (counter-clockwise) direction until the desired <i>Clip Arm Angle</i> is achieved. 5. <i>Lock the Clip</i>. <p>CAUTION: Always <i>Lock the Clip</i> immediately after the desired <i>Clip Arm Angle</i> is achieved. Device damage may occur.</p> <p>NOTE 1: If Clip does not open smoothly, retract the Lock Lever farther, then repeat steps 2 – 5.</p> <p>NOTE 2: If the Clip Arms fail to open visibly (as observed under fluoroscopic guidance), use the following techniques in the order provided, as needed:</p> <ol style="list-style-type: none"> A. Stop and return <i>Arm Positioner to Neutral</i>. Retract Lock Lever farther, then turn the Arm Positioner farther in the “Close” direction before turning in the “Open” direction. B. Turn the <i>Arm Positioner to Neutral</i>, then incrementally iterate the amount of Arm Positioner rotation in the “Close” direction followed by rotation in the “Open” direction. Iterate until Clip opens or until it is no longer possible to rotate the Arm Positioner in the “Close” direction. C. Turn the <i>Arm Positioner to Neutral</i>, iterate the amount of Lock Lever retraction past the mark in 5 mm increments, and rotate the Arm Postioner fully in the “Close” direction, before rotating in the “Open” direction, until Clip opens. D. Advance the Gripper Lever and repeat NOTE 2, Step C. Retract the Gripper Lever after Clip opens. E. If the Clip is in the LA and free of tissue, release the DC Fastener, then release the Sleeve curves and repeat NOTE 2, Step C. <p>WARNING: Failure to release the DC Fastener before releasing Sleeve curves may result in device damage and/or embolization.</p> <ol style="list-style-type: none"> F. If the Clip does not open after performing all steps in NOTE 2, DO NOT use the device.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 20 of 39	

<i>Arm Positioner to Neutral</i>	Turn the Arm Positioner in the “Close” or “Open” direction until no resistance to turning is noted.
<i>Invert the Clip Arms</i>	<ol style="list-style-type: none"> 1. Unlock the Clip. 2. Turn the Arm Positioner at least 1/2 turn in the “Close” direction. 3. Turn the Arm Positioner in the “Open” direction until the Clip Arms invert (see Figure 6F). DO NOT over-invert the Clip Arms; stop turning the Arm Positioner when resistance is first noted. 4. <i>Lock the Clip.</i>
<i>Raise the Grippers</i>	<ol style="list-style-type: none"> 1. Rotate the Gripper Lever outward. 2. Slowly retract the Gripper Lever (under fluoroscopic observation) until the mark on the lever is just exposed. NOTE: If pulling beyond the mark is required, advance the Gripper Lever back to the mark once the Grippers are fully raised. 3. Rotate the Gripper Lever inward to engage the lever.
<i>Lower the Grippers</i>	<ol style="list-style-type: none"> 1. Rotate the Gripper Lever outward. 2. Fully advance the Gripper Lever. 3. Rotate the Gripper Lever inward to engage the lever.
<i>Clip Arm Angle</i>	<ul style="list-style-type: none"> • Angle between the inner edges of both Clip Arms. • All <i>Clip Arm Angles</i> are measured using fluoroscopy with optimal view in plane of “V” (see Figure 6).
<i>Grasping Arm Angle</i>	A <i>Clip Arm Angle</i> of approximately 120 degrees. NOTE: Establish <i>Grasping Arm Angle</i> after closing the Clip from a larger <i>Clip Arm Angle</i> .
<i>Fully Close the Clip Arms</i>	Turn the Arm Positioner in the “Close” direction until the Clip Arms contact the DC. <ul style="list-style-type: none"> • Under direct visualization, the Clip is fully closed when the Clip Covering contacts the DC. • Under fluoroscopic observation, the Clip is fully closed when the inner edges of the Clip Arms are parallel. CAUTION: Never close the Clip while the Lock Lever is in an unlocked state. Device damage may occur.
<i>Establish Final Arm Angle</i>	Pre-deployment <i>Clip Arm Angle</i> that reflects the <i>Clip Arm Angle</i> post-deployment. <ol style="list-style-type: none"> 1. With the Lock Lever fully advanced, turn the Arm Positioner in the “Open” direction until resistance is first noted. The Clip Arms may open slightly and then remain in a stable position. 2. Confirm that the Clip is locked by observing slight Delivery Catheter shaft deflection using fluoroscopy. NOTE: If continued opening of the Clip Arms is noted, reconfirm that the Lock Lever is completely advanced. Close the Clip Arms, and <i>Establish Final Arm Angle</i> .

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 21 of 39	

2.0 PATIENT PREPARATION

- 2.1 Prepare the patient per institution's standard practice for transseptal catheterization.
- 2.2 Place support plate under patient's leg in the region between the area of the upper leg and the knee and place the Lift over the ipsilateral lower extremity prior to draping the patient.
- 2.3 Place the Lift on the Support Plate such that the front edge (i.e., the edge that corresponds with the shorter legs of the Lift) is approximately 80 cm from the patient's mid sternum.
- 2.4 Adjust the height of the Lift so that the front edge of the Lift is close to the patient's leg, but is not impinging on it. Adjust the back legs to be 2 or 3 notches above the front legs (i.e., the back legs of the Lift are taller than the front legs).
- 2.5 Ensure the Lift and Support Plate are covered completely by sterile drape during the procedure. Use towels as necessary to minimize direct contact between the patient and all surfaces of both the Lift and Support Plate.
- 2.6 Prepare the patient for invasive hemodynamic monitoring.

3.0 MITRACLIP SYSTEM PREPARATION BEFORE USE

- WARNING:** DO NOT use the MitraClip System after the "Use By" date stated on the package label, and never reuse or re-sterilize the system.
- WARNING:** Always inspect the MitraClip System and its packaging to verify no damage has occurred as a result of shipping and handling and that the sterile barrier has not been compromised. DO NOT use the device if damage is detected.
- WARNING:** DO NOT remove the protective cover placed over the Clip. DO NOT handle the Clip directly; leave it in the protective cover to avoid potential contamination.
- The preparation is most easily accomplished with the aid of an assistant.

3.1 STEERABLE GUIDE CATHETER PREPARATION

- WARNING:** All lumens contain air when shipped. Use proper de-airing techniques before and during use to minimize the risk of air embolization.
- 3.1.1 Carefully remove the white Guide tip shape retainer and transparent protective tubing from the Guide tip.
 - 3.1.2 Inspect Steerable Guide Catheter and Dilator to verify they are undamaged.

CAUTION: DO NOT use if damage is detected.
 - 3.1.3 Remove the sterile package containing Fasteners and Silicone Pad from the Steerable Guide Catheter tray.
 - 3.1.4 Fill a basin with 1000 cc of heparinized saline.
 - 3.1.5 Flush and de-air the Guide and Dilator with heparinized saline:
 - 3.1.5.1 Connect 3-way stopcocks to the Guide and Dilator flush ports.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 22 of 39	

3.1.5.2 De-air the Dilator, then close the stopcock and the Rotating Hemostatic Valve.

3.1.5.3 Hydrate 5-10 cm of the distal end of the Dilator with heparinized saline.

3.1.5.4 Insert the Dilator approximately 10 cm into Guide then remove.

3.1.5.5 Connect high pressure tubing and a 50-60 cc syringe filled with heparinized saline to the Guide flush port.

3.1.5.6 De-air the Guide.

3.1.5.6.1 With the tip raised, displace all air from the Guide while tapping along the length of the catheter shaft.

3.1.5.6.2 Cover the Guide tip with finger once heparinized saline exits the Guide.

3.1.5.6.3 Close the Guide stopcock.

3.1.6 Submerge the Guide tip in the basin of heparinized saline.

3.1.7 While the Guide tip is submerged in the basin of heparinized saline, remove finger from Guide tip and check the Guide valve for leaks by raising the handle to a vertical position for a minimum of 30 seconds.

3.1.8 Hydrate 5-10 cm of the distal end of the Dilator with heparinized saline.

3.1.9 Cover the Guide tip with finger and insert the Dilator into the Guide while Guide tip remains submerged in the basin of heparinized saline.

3.1.9.1 While advancing the Dilator, continually watch for air in the Guide Hemostasis Valve housing. If needed, remove finger from Guide tip and aspirate while assuring the Guide tip is submerged.

3.1.9.2 Remove finger from tip of Guide when the Dilator tip approaches the Guide tip.

3.1.9.3 Advance the Dilator until the curve is extended from the Guide tip.

3.2 STEERABLE GUIDE CATHETER FUNCTIONAL INSPECTION

- The functional inspection is most easily accomplished with the aid of an assistant.
- The Guide functional inspection should be performed with the Guide tip and Dilator tip submerged in a basin of heparinized saline to prevent air from entering the lumens. If the Guide tip and/or Dilator tip fails to remain submerged during inspection, flush the Guide and/or Dilator with heparinized saline to completely remove air.

WARNING: Failure to completely remove air may result in air embolization.

CAUTION: All catheter manipulations should be done with care. DO NOT continue to rotate or manipulate any of the handle controls if significant resistance is noted. Device damage may occur.

Guide Inspection

3.2.1 Inspect all Guide parts to verify they are undamaged.

CAUTION: DO NOT use device if damage is detected.

3.2.2 To confirm proper tip deflection with “+” knob rotation:

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 23 of 39	

- 3.2.2.1 Rotate the +/- Knob in the "+" direction until the Guide is curved to approximately 80 degrees.
- 3.2.2.2 Remove hand from the +/- Knob and check that the knob does not slip.
- 3.2.2.3 Return the +/- Knob to the neutral position.
- 3.2.2.4 Repeat steps 3.2.2.1 through 3.2.2.3.
- 3.2.3 To confirm proper tip deflection with "-" knob rotation:
 - 3.2.3.1 Rotate the +/- Knob in the "-" direction until the Guide curve is substantially straightened.
 - 3.2.3.2 Remove hand from the +/- Knob and check that the knob does not slip.
 - 3.2.3.3 Return the +/- Knob to the neutral position.
 - 3.2.3.4 Repeat steps 3.2.3.1 through 3.2.3.3.
- 3.2.4 Retract the Dilator until the tip is 3-5 cm beyond the Guide tip. Position the Dilator to create a smooth transition.

3.3 STABILIZER PREPARATION

- 3.3.1 Assemble the sterilized Stabilizer by placing the two Fasteners in the Stabilizer. Ensure that the Fasteners can be fully threaded into the Stabilizer holes. Set the Stabilizer aside in a protected sterile environment for later use.

3.4 CLIP DELIVERY SYSTEM PREPARATION

- 3.4.1 Inspect the Clip, DC shaft, and Sleeve tip to verify they are undamaged.

CAUTION: DO NOT use the device if damage is detected.

Sleeve Preparation

- 3.4.2 Connect 3-way stopcocks to the Sleeve flush port and bottom DC flush port.
- 3.4.3 Remove the cap from the Clip Introducer.
- 3.4.4 Place the cap on the top flush port of the DC Handle.
- 3.4.5 Connect a 3-way stopcock to the Clip Introducer flush port.
- 3.4.6 Connect one high pressure tube to each drip line from the pressurized bags with sterile heparinized saline; flush and de-air the lines.
- 3.4.7 Connect one high pressure tube to the 3-way stopcock on the bottom flush port of the DC Handle and one high pressure tube to the 3-way stopcock on the flush port of the Sleeve Handle.
- 3.4.8 Flush and de-air the Sleeve with heparinized saline.
 - 3.4.8.1 With the tip raised and the shaft held taut, displace all air from the Sleeve lumen while tapping along the length of the catheter shaft.
 - 3.4.8.2 While flushing, release the DC Fastener, retract and advance the DC Handle to remove residual air from the lumen.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 24 of 39	

WARNING: Using excessive force when pulling the DC Radiopaque Ring against the Sleeve tip, while translating the DC shaft, may result in device damage including distal embolization.

3.4.8.3 Secure the DC Fastener with DC Handle fully advanced.

Delivery Catheter Preparation

WARNING: DO NOT handle the Clip directly; leave in the protective cover to avoid potential contamination.

- 3.4.9 Attach a 50-60 cc syringe filled with heparinized saline to the 3-way stopcock on the Clip Introducer.
- 3.4.10 De-air the Clip Introducer, then close the stopcock.
- 3.4.11 Temporarily remove the cap from top flush port of the DC Handle.
- 3.4.12 Flush and de-air DC Handle and all lumens of the DC with heparinized saline.
- 3.4.13 After de-airing the DC Handle chamber, replace the cap to close off top flush port of the DC Handle.
- 3.4.14 Retract and advance the Lock Lever several times to remove residual air from the lumens.
- 3.4.15 Loosen the Lock Lever and the Gripper Lever Caps to de-air. DO NOT turn lever caps more than 1/2 turn in the "Open" direction. After de-airing, tighten the lever caps.
- 3.4.16 With the tip raised and the shaft held taut, displace all air from the DC while tapping along the length of the catheter shaft.
- 3.4.17 Confirm continuous flow from the distal end of the DC.

3.5 CLIP DELIVERY SYSTEM FUNCTIONAL INSPECTION

- The functional inspection is most easily accomplished with the aid of an assistant.
- 3.5.1 Inspect all Clip Delivery System parts, including the Clip, to verify they are undamaged.

CAUTION: DO NOT use device if damage is detected.

CAUTION: All catheter manipulations should be done with care. DO NOT continue to rotate or manipulate any of the handle controls if significant resistance is noted. Device damage may occur.

Sleeve Inspection

CAUTION: DO NOT deflect the Sleeve more than 90 degrees during the inspections below.

3.5.2 To confirm proper tip deflection with "A" knob rotation:

- 3.5.2.1 With the DC handle fully advanced and the shaft held taut, rotate the A/P Knob approximately 3/4 turn in the "A" direction from neutral to confirm that the distal tip deflects.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 25 of 39	

3.5.2.2 Remove hand from the A/P Knob and check that the knob does not slip.

3.5.2.3 Return the A/P Knob to the neutral position.

3.5.2.4 Repeat steps 3.5.2.1 through 3.5.2.3.

3.5.3 To confirm proper tip deflection with "P" knob rotation:

3.5.3.1 With the DC handle fully advanced and the shaft held taut, rotate the A/P Knob approximately 3/4 turn in the "P" direction from neutral to confirm that the distal tip deflects.

3.5.3.2 Remove hand from the A/P Knob and check that the knob does not slip.

3.5.3.3 Return the A/P Knob to the neutral position.

3.5.3.4 Repeat steps 3.5.3.1 through 3.5.3.3.

3.5.4 To confirm proper tip deflection with "M" knob rotation:

3.5.4.1 With the DC Handle fully advanced and the shaft held taut, rotate the M/L Knob in the "M" direction until the distal tip deflects to approximately 90 degrees to confirm distal tip deflection.

3.5.4.2 Remove hand from the M/L Knob and check that the knob does not slip.

3.5.4.3 Return the M/L Knob to the neutral position.

3.5.4.4 Repeat steps 3.5.4.1 through 3.5.4.3.

Delivery Catheter and Clip Inspection

WARNING: DO NOT handle the Clip directly, leave in the protective cover to avoid potential contamination.

NOTE: If *Clip Arm Angle* is greater than *Grasping Arm Angle*, close the Clip to *Grasping Arm Angle*; if *Clip Arm Angle* is less than *Grasping Arm Angle*, *Unlock the Clip and Open the Clip Arms* to 180 degrees then close the Clip to *Grasping Arm Angle*.

3.5.5 Carefully inspect the Grippers to confirm the cover is intact and not damaged.

CAUTION: DO NOT use the device if damage is detected.

3.5.6 *Raise the Grippers.*

CAUTION: Raising the Grippers more often than needed, retracting the Gripper Lever forcefully, or retracting the Gripper Lever more than 1.5 cm beyond the mark may damage the Gripper cover and impair CDS performance.

3.5.7 Unlock the Clip.

WARNING: Retracting the Lock Lever forcefully may result in the inability to lock or unlock the Clip.

3.5.8 *Invert the Clip Arms.*

CAUTION: DO NOT continue turning the Arm Positioner if resistance is felt; device damage may occur.

3.5.9 *Lock the Clip.*

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 26 of 39	

3.5.10 Close the Clip to *Grasping Arm Angle*.

3.5.11 *Lower the Grippers* once to de-air the lumens.

3.5.12 Release the DC Fastener and torque the DC Handle clockwise and counterclockwise 1/4 turn while translating the shaft.

WARNING: Using excessive force when pulling the DC Radiopaque Ring against the Sleeve tip, while translating the DC shaft, may result in device damage including distal tip embolization.

3.5.13 Secure the DC Fastener with DC Handle fully advanced.

3.5.14 Close the Clip to a *Clip Arm Angle* of approximately 20 degrees.

3.5.15 *Establish Final Arm Angle*.

3.5.16 Return the *Arm Positioner to Neutral*.

3.5.17 Unlock the Clip.

3.5.18 Open the Clip to *Grasping Arm Angle*.

3.5.19 *Lock the Clip*.

3.5.20 Return the *Arm Positioner to Neutral*.

3.5.21 Release the DC Fastener and retract the DC fully against the Sleeve.

3.5.22 Secure the DC Fastener.

3.5.23 Temporarily discontinue heparinized saline flushes.

The following steps should be performed just before use of the CDS:

3.5.24 Re-start heparinized saline flushes.

3.5.25 *Raise the Grippers*.

3.5.26 *Fully Close the Clip Arms*.

3.5.27 *Lower the Grippers*.

3.5.28 Without removing the protective cover, carefully slide the Clip Introducer over the Clip.

CAUTION: DO NOT compress the Clip Arms. Compressing the Clip Arms may result in inability to open the Clip.

3.5.29 Stop when the tip of the Clip is just proximal to the tip of the Clip Introducer.

3.5.30 Turn the *Arm Positioner to Neutral*.

CAUTION: Failure to *Fully Close the Clip Arms*, before insertion or retraction into the Clip Introducer, may result in difficulty or inability to advance or retract the Clip.

WARNING: Heparinized saline flush should be continuous throughout the procedure. Ensure flow is visible through the drip chamber, that the tubing is free from kinks and/or obstruction and appropriate pressure of 300 mm Hg is maintained. Discontinuing flush may result in air embolism and/or thrombus formation.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 27 of 39	

4.0 ACCESS TO THE MITRAL VALVE

NOTE: This is a suggested sequence for the procedure. Variations may be used based upon patient anatomy.

4.1 Access the LA to accommodate the Guide tip using transvenous, transseptal techniques and equipment.

4.2 Heparinize the patient.

WARNING: Failure to administer heparin once transseptal access has been achieved may result in thrombus formation.

4.3 Carefully place a 260 cm super stiff 0.035" exchange length guidewire in the left upper pulmonary vein or LA. Dilate the subcutaneous tissue and femoral vein to accommodate the Guide shaft using standard dilation technique.

5.0 STEERABLE GUIDE CATHETER INSERTION

WARNING: Confirm a smooth transition between the Dilator and the atraumatic tip of the Guide to minimize the risk of cardiovascular injury.

CAUTION: Always use pressure monitoring, echocardiography and fluoroscopy for guidance and observation during use of the MitraClip System.

CAUTION: Always use a careful, deliberate, and iterative approach to positioning the MitraClip System. It is recommended to make multiple small adjustments rather than single large adjustments.

5.1 Rotate the +/- Knob in the "-" direction until the Guide curve is substantially straightened.

5.2 Wet the surface of the Guide shaft with sterile saline.

5.3 Insert the Guide-Dilator assembly over the stationary guidewire into the femoral vein.

WARNING: DO NOT use excessive force to advance or manipulate the Guide-Dilator assembly. If resistance is encountered, use echocardiography and/or fluoroscopy to assess before proceeding to prevent patient injury.

5.4 Advance the Guide-Dilator assembly to the RA. Rotate the +/- Knob to Neutral, then place tip of the Dilator partially across the atrial septum.

5.5 Slowly dilate the atrial septum by gradually advancing the tip of the Guide-Dilator assembly.

WARNING: DO NOT rapidly advance the Guide-Dilator assembly across the atrial septum. Tissue injury may result.

5.6 Advance the Guide-Dilator assembly until the tip of the Guide extends approximately 3 cm in the LA.

5.7 Adjust Guide deflection and torque to position the tip away from adjacent tissues.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 28 of 39	

- 5.8 Place the Silicone Pad on the sterile drape over the Lift. Place the Stabilizer onto the Silicone Pad.
- 5.9 Secure the Guide in the Stabilizer slot using the Fastener. Ensure the Fastener engages the metallic tube on the Guide shaft. The Guide handle should be immediately adjacent to the Stabilizer, such that they are in contact with each other.
- 5.10 Retract the Dilator approximately 5 cm into the Guide, leaving the guide wire in the left upper pulmonary vein or LA .

CAUTION: Always loosen the Fastener before torquing the Guide to prevent device damage.

- 5.11 Retract the guidewire into the tip of the Dilator. Remove the Dilator and guidewire while gently aspirating the Guide (starting when the Dilator is approximately halfway retracted into the Guide, approximately 40 cm) using a 50-60 cc syringe. Cover Guide Hemostasis Valve with finger upon Dilator removal.

NOTE: Avoid contacting tissue or creating a vacuum in the Guide lumen. If necessary, position the Guide handle below the level of the LA to allow blood to fill the Guide lumen.

WARNING: DO NOT create a vacuum while removing the dilator from the Guide; air may enter the lumen of the Guide. Patient injury may result.

WARNING: Failure to fully retract guidewire into the Dilator may result in air embolization.

6.0 CLIP DELIVERY SYSTEM INSERTION

- 6.1 Confirm the Guide lumen is completely de-aired.

WARNING: To minimize the potential of air embolism, DO NOT introduce the CDS into the Guide until the Guide lumen has been completely de-aired. Patient injury may result.

- 6.2 Confirm there is a slow, continuous heparinized saline flush through both the Sleeve and the DC.

CAUTION: Failure to continuously flush the CDS with heparinized saline may reduce device performance.

WARNING: Heparinized saline flush should be continuous throughout the procedure. Ensure flow is visible through the drip chamber and that tubing is free from kinks and/or obstruction and pressure of 300 mm Hg is maintained. Discontinuing flush may result in air embolism and/or thrombus formation.

- 6.3 Confirm tip of the Clip is just proximal to the tip of the Clip Introducer.
- 6.4 Carefully remove the protective cover surrounding the Clip and the Clip Introducer.
- 6.5 Confirm that the stopcock on the Clip Introducer flush port is closed and that the Clip Introducer is de-aired.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 29 of 39	

- 6.6 While flushing heparinized saline on the Guide Hemostasis Valve, place the tip of the Clip Introducer against the Guide Hemostasis Valve and advance the Clip Introducer straight into the valve in a continuous motion while rotating the Clip Introducer in small clockwise and counterclockwise motions until the Clip can be observed distal to the valve.

CAUTION: DO NOT continue to advance the Clip Introducer if resistance is felt; the Guide Hemostasis Valve, Clip Introducer or the Clip may be damaged.

WARNING: To minimize the potential of air embolization, ensure proper de-airing when inserting the Clip Introducer into the Guide Hemostasis Valve.

- 6.7 Leave the Clip Introducer fully inserted in the Guide Hemostasis Valve throughout the procedure.
- 6.8 Align the Longitudinal Alignment Marker on the Sleeve shaft with the Alignment Marker on the Guide Hemostasis Valve.
- 6.9 Carefully advance the CDS through the Guide under fluoroscopic guidance. Stop when the tip of the Clip is even with the tip of the Guide.
- NOTE:** If resistance to CDS advancement is felt, reduce Guide deflection.
- 6.10 Under echocardiographic guidance, advance the CDS and retract the Guide iteratively as needed while maintaining the Guide in the LA. Stop when the Guide RO Tip Ring is between the RO Alignment Markers of the Sleeve, as confirmed under fluoroscopic guidance.
- 6.11 Position the Sleeve Handle in the Stabilizer slot.
- 6.12 Confirm that the Clip is free from the left atrial wall and valve tissue.

CAUTION: Failure to confirm that the Clip is free from the left atrial wall and valve tissue may result in patient injury.

7.0 INITIAL MITRACLIP SYSTEM POSITIONING IN THE LEFT ATRIUM

NOTE: Positioning is achieved with iterative adjustments of the Guide and CDS using torque, translation and knob adjustments. The goals of positioning are:

- A. Positioning the Clip centrally over the valve with respect to anterior-posterior and medial-lateral directions.
- B. Aligning the Clip so the DC Shaft is perpendicular to the plane of the mitral valve.
- C. Positioning the distal tip of the Clip at least 1 cm above the leaflets.

WARNING: Excessive torque on the Guide and translation of the MitraClip System may inadvertently displace the tip of the Guide from the LA, which may result in patient injury.

CAUTION: DO NOT continue to rotate or manipulate any of the handle knobs if significant resistance is noted; device damage may occur.

- 7.1 Adjust the Guide position as necessary to maintain that the Clip is free from adjacent tissue.
- 7.2 Adjust Sleeve deflection using the M/L Knob and/or the A/P Knob to deflect the Clip towards

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 30 of 39	

the apex. Retract the DC Radiopaque Ring against the Sleeve tip as necessary.

- 7.3 During Sleeve deflections confirm that the Guide RO Tip Ring is between the RO Alignment Markers of the Sleeve prior to making maximum Sleeve deflections.

CAUTION: DO NOT deflect the Sleeve tip more than 90 degrees as device damage may occur.

- 7.4 Secure the Sleeve handle in the Stabilizer using the Fastener.
- 7.5 To reposition the MitraClip System, move the Stabilizer and the system together until positioning is adequate.
- 7.6 Adjust the MitraClip System position to maintain adequate height above the mitral valve in the LA.

CAUTION: Maintain the Clip above the leaflets until ready to grasp to minimize the risk of Clip entanglement in the chordal apparatus.

8.0 FINAL MITRACLIP SYSTEM POSITIONING

- 8.1 *Raise the Grippers*

CAUTION: Raising the Grippers more often than needed, retracting the Gripper Lever forcefully, or retracting the Gripper Lever more than 1.5 cm beyond the mark may damage the Gripper cover and impair CDS performance.

- 8.2 *Unlock the Clip and Open the Clip Arms* to approximately 180 degrees.

WARNING: Retracting the Lock Lever forcefully may result in the inability to unlock Clip. Intervention may be required.

- 8.3 *Lock the Clip.*

CAUTION: Failure to immediately advance the Lock Lever after Clip Arm opening may affect DC shaft straightness.

- 8.4 Adjust the MitraClip System to reposition the Clip as necessary. Confirm that the distal tip of the Clip is at least 1 cm above the leaflets.
- 8.5 Rotate the DC handle to align the Clip Arms perpendicular to the line of coaptation. DO NOT rotate the Clip more than 90 degrees in each direction.
- 8.6 Carefully translate the DC shaft multiple times to release stored torque. Fully retract the DC.

CAUTION: Failure to fully release stored torque may result in unwanted Clip Arm orientation changes during grasping. Torque of the DC Handle more than 180 degrees may result in DC damage.

- 8.7 Complete final MitraClip System positioning in the LA using multiple imaging planes. Re-secure the Guide and Sleeve Fasteners.

9.0 GRASPING THE LEAFLETS AND VERIFYING THE GRASP

- 9.1 Advance the DC distally to position the Clip approximately 2 cm below the valve. Ensure that the Clip Arms are oriented perpendicular to the line of coaptation.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 31 of 39	

- WARNING:** Failure to confirm that the Clip Arms are perpendicular to the line of coaptation may result in loss of leaflet capture and insertion.
- WARNING:** DO NOT make substantial Clip Arm orientation adjustment in the LV. Clip entanglement in sub-valvular apparatus may result in difficulty or inability to remove the Clip.
- WARNING:** Always ensure that either the Grippers are raised or that the Clip is closed while in the LV to avoid potential tissue damage.

9.2 Close the Clip to the *Grasping Arm Angle*.

9.3 Without using excessive force, retract the DC to grasp both anterior and posterior leaflets.

- WARNING:** An improper grasp will allow one or both leaflets to move freely. Closing and deploying the Clip in this situation may result in loss of leaflet capture and insertion.

9.4 If the grasp appears satisfactory, *Lower the Grippers* onto the leaflets.

- WARNING:** Failure to confirm that both Grippers have been lowered onto the leaflets prior to closing the Clip may result in loss of leaflet capture and insertion.

- WARNING:** DO NOT adjust the position of the MitraClip System after grasping the leaflets, valve injury may occur.

9.5 Close the Clip until the *Clip Arm Angle* is approximately 60 degrees. Release tension on the DC and secure the DC Fastener.

9.6 Use echocardiographic imaging to verify insertion of both leaflets and satisfactory grasp by observation of:

- Leaflet immobilization;
- Single or multiple valve orifice(s);
- Limited leaflet mobility relative to the tips of both Clip Arms;
- Adequate MR reduction.

9.6.1 If grasping fails to hold both leaflets and the Clip retracts to the LA, reposition the MitraClip System.

9.6.1.1 *Unlock the Clip and Open the Clip Arms* to approximately 180 degrees and reorient the Clip Arms in the LA, as needed, then repeat grasping steps.

9.6.1.1.1 If significant repositioning is necessary, *Fully Close the Clip Arms* and *Lower the Grippers* then repeat positioning and grasping steps.

9.6.2 If the Sleeve limits DC travel during grasping, an inadequate grasp may require repositioning of the MitraClip System.

9.6.2.1 *Raise the Grippers, Unlock the Clip and Open the Clip Arms* to 180 degrees, and advance the DC handle. Repeat positioning and grasping steps as necessary.

10.0 CLOSING THE CLIP AND EVALUATING CLIP POSITION

10.1 Slowly close the Clip just until the leaflets are coapted and MR is sufficiently reduced. The Clip should maintain a distinct "V" shape.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 32 of 39	

WARNING: DO NOT use excessive force to close the Clip further than is necessary to adequately reduce MR. Leaflet injury may occur.

CAUTION: Closing the Clip too tightly may result in inability to deploy the Clip.

10.2 Use echocardiographic imaging to verify valve function, satisfactory coaptation, and insertion of both leaflets by observation of:

- Leaflet immobilization;
- Single or multiple valve orifice(s);
- Limited leaflet mobility relative to the tips of both Clip Arms;
- Adequate MR reduction.

10.2.1 If the Clip position is not satisfactory, *Raise the Grippers* and *Invert the Clip Arms*.

10.2.2 Retract the inverted Clip into the LA.

10.2.3 Confirm both leaflets move freely.

10.2.4 Repeat positioning steps, as necessary, then repeat grasping steps.

11.0 MITRACLIP DEVICE PRE-DEPLOYMENT CLIP ASSESSMENT

11.1 Confirm DC Handle is secure.

WARNING: Failure to secure the DC Handle may result in leaflet injury or loss of leaflet insertion.

11.2 *Establish Final Arm Angle.*

CAUTION: DO NOT turn the Arm Positioner more than 1/2 turn in the “Open” direction once initial resistance is felt. Device damage may occur.

11.3 Turn the Arm Positioner to the “closed” side of the neutral position.

11.3.1 Use echocardiographic imaging to verify valve function, satisfactory coaptation, and insertion of both leaflets by observation of:

- Leaflet immobilization;
- Single or multiple valve orifice(s);
- Limited leaflet mobility relative to the tips of both Clip Arms;
- Adequate MR reduction.

11.4 Perform mean pressure gradient assessment prior to proceeding to deployment.

11.5 Establish Gripper Line Removability.

WARNING: Failure to Establish Gripper Line Removability prior to deployment of the Clip may result in inability to remove the Gripper Line. Intervention may be required.

11.5.1 Confirm the Gripper Lever is fully advanced.

11.5.2 Increase the flush rate to the DC and Sleeve. Remove the Gripper Lever Cap and “O” ring. Unwrap the two ends of the Gripper Line. Remove the plastic cover from the lines and separate the two ends so that no twists or knots are present.

11.5.3 With one free end of the Gripper Line in each hand, confirm that the Gripper Line is

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 33 of 39	

removable by pulling slowly on one end until the other end of the Gripper Line moves approximately 3-5 cm. If the Gripper Line is confirmed to be removable, continue to Clip Deployment.

NOTE: If excessive resistance is noted, stop, and pull on the other free end.

CAUTION: While Establishing Gripper Line Removability, ensure that both ends of the Gripper Line remain exposed.

WARNING: Pulling the Gripper Line too quickly or with excessive force may raise the Grippers, break the Gripper Line and/or disturb leaflet capture and insertion. Intervention may be required.

11.5.3.1 If excessive resistance is noted at both ends of the Gripper Line (resulting in failure to Establish Gripper Line Removability), stop and remove the Clip Delivery System.

NOTE: The removal of the Clip Delivery System is most easily accomplished with the aid of an assistant.

11.5.3.1.1 Hold both free ends of the Gripper Lines together and apply tension to maintain the Grippers in a raised position through Step 11.5.3.1.4.

11.5.3.1.2 *Invert the Clip Arms* and then *Lock the Clip*.

11.5.3.1.3 Release the DC Fastener and retract the inverted Clip into the LA. Retract DC shaft until the DC Radiopaque Ring is fully against the tip of the Sleeve.

11.5.3.1.4 *Fully Close the Clip Arms*.

11.5.3.1.5 Continue to Section 14.2.1.5: MITRACLIP SYSTEM REMOVAL WITH CLIP ATTACHED to remove the Clip.

12.0 CLIP DEPLOYMENT

12.1 Deployment Step 1: Lock Line Removal

12.1.1 Remove the Lock Lever Cap and "O" ring. Unwrap the two ends of the Lock Line. Remove the plastic cover from the lines so that that no twists or knots are present.

12.1.2 Grasp one of the free ends of the Lock Line, confirm the line moves freely, and slowly remove the Lock Line. Pull the Lock Line coaxial to the Lock Lever. If resistance is noted, stop and pull on the other free end to remove the Lock Line.

12.1.3 *Establish Final Arm Angle*.

NOTE: The Clip Arms may open slightly before remaining in a stable position. If Arms open more than slightly, close the Clip to the desired Arm position and re-*Establish Final Arm Angle*.

12.1.4 Turn the *Arm Positioner to Neutral*.

12.2 Deployment Step 2: Delivery Catheter Shaft Detachment

12.2.1 Confirm that the Arm Positioner is Neutral and that the two ends of the Gripper Line have been unwrapped from under the cap and are not twisted or knotted. Remove the release pin from the DC Handle.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 34 of 39	

12.2.2 Turn the Actuator Knob of the DC approximately 8 turns counterclockwise. If it is difficult to turn the Actuator Knob, confirm that the Arm Positioner moves freely.

CAUTION: Failure to stop turning the Actuator Knob when resistance is felt or turning the Actuator Knob in the clockwise direction may result in inability to deploy the Clip.

12.2.3 Release the DC Fastener then retract the Actuator Knob after it is fully unthreaded.

12.2.4 Confirm that the Release Pin groove is fully exposed.

12.2.5 Retract the DC Handle such that the Clip has separated at least 1 cm from the DC tip.

12.2.6 Secure the DC Fastener.

12.2.7 Allow several minutes after catheter shaft detachment before proceeding to the final Clip deployment step. Use echocardiographic imaging to verify valve function, satisfactory coaptation, and insertion of both leaflets by observation of:

- Leaflet immobilization;
- Single or multiple valve orifice(s);
- Limited leaflet mobility relative to the tips of both Clip Arms;
- Adequate MR reduction.

WARNING: If Clip placement and/or MR reduction is not satisfactory after Deployment Step 2: Delivery Catheter Shaft Detachment, DO NOT proceed to Deployment Step 3: Gripper Line Removal. Intervention may be required to remove the Clip.

12.3 Deployment Step 3: Gripper Line Removal

12.3.1 Grasp one of the free ends of the Gripper Line, confirm the line moves freely and slowly remove the line. Pull the Gripper Line coaxial to the Gripper Lever. If resistance is noted, stop and pull on the other free end to remove the Gripper Line. Maintain at least 1 cm separation between the DC tip and the Clip while slowly removing the Gripper Line.

WARNING: If less than 1 cm separation is present between the DC tip and the Clip before or during Gripper Line retraction, removal may be impaired.

WARNING: Pulling the Gripper Line too quickly or with excessive force may raise the Grippers, resulting in device damage and/or compromise leaflet capture and insertion.

12.3.1.1 If the Gripper Line does not move easily, release the DC Fastener and incrementally release Sleeve curves (M/L Knob and A/P Knob). Secure DC Fastener once Sleeve curves are released.

WARNING: Failure to release the DC Fastener before releasing Sleeve curves may result in device damage and/or embolization.

12.3.1.2 If the Gripper Line still does not move easily, partially release Guide curves.

12.3.1.3 If the Gripper Line still does not move easily, the CDS may also be partially retracted into the tip of the Guide, or completely removed by pulling only on the Sleeve Handle, to facilitate Gripper Line removal.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 35 of 39	

WARNING: Retracting the CDS by pulling on the DC Handle may result in device damage and/or embolization.

12.3.2 Release the DC Fastener and retract the DC Handle until the DC Radiopaque Ring is against the tip of the Sleeve.

12.3.3 Secure the DC Fastener.

12.3.4 Confirm that the Clip position is stable.

12.3.5 Use echocardiographic imaging to verify valve function, satisfactory coaptation, and insertion of both leaflets by observation of:

- Leaflet immobilization;
- Single or multiple valve orifice(s);
- Limited leaflet mobility relative to the tips of both Clip Arms;
- Adequate MR reduction.

12.4 If placing an additional Clip proceed to Section 13.0. If not placing an additional Clip proceed to section 14.0.

13.0 Additional MITRACLIP DEVICE PLACEMENT

WARNING: Use caution not to displace or dislodge an implanted Clip when placing an additional Clip; Clip detachment from leaflet(s) may occur.

13.1 When placing an additional Clip, the following are recommended:

13.1.1 In the LA, ensure Clip Arms are oriented perpendicular to the line of coaptation and Grippers are raised.

13.1.2 Cross into the LV with a *Clip Arm Angle* of <90 degrees.

13.1.3 Use both fluoroscopy and echocardiography when crossing into the LV and during grasping.

13.1.4 *Unlock the Clip and Open the Clip Arms* to 180 degrees. Ensure that the Clip Arms are oriented perpendicular to the line of coaptation then Close the Clip to the *Grasping Arm Angle*.

WARNING: DO NOT use excessive force or retraction distance during grasping. This may compromise leaflet capture and insertion. Intervention may be required.

14.0 MITRACLIP SYSTEM REMOVAL

WARNING: During MitraClip System removal always retract the CDS by pulling only on the Sleeve Handle. Retracting the CDS by pulling on the DC Handle may result in device damage and/or embolization.

WARNING: Failure to release the DC Fastener before releasing Sleeve curves may result in device damage and/or embolization.

WARNING: Failure to utilize echocardiographic guidance while releasing Sleeve deflection may result in patient injury.

14.1 MITRACLIP SYSTEM REMOVAL AFTER CLIP DEPLOYMENT

14.1.1 Removal of the CDS While Leaving the Guide in Place.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 36 of 39	

- 14.1.1.1 Release the DC Fastener.
- 14.1.1.2 Slowly release Sleeve deflection by rotating the M/L Knob and the A/P Knob to neutral.
- 14.1.1.3 Secure DC Fastener once Sleeve curves are released.
- 14.1.1.4 Straighten the Guide with the +/- Knob when the Delivery Catheter tip is free from the left atrial wall and the mitral valve.
- 14.1.1.5 Release the Sleeve Fastener and retract the CDS approximately 10 cm into the Guide by pulling only on the Sleeve Handle.
- 14.1.1.6 Confirm that the Clip Introducer is still fully advanced in the Guide Hemostasis Valve.
- 14.1.1.7 Retract the CDS by pulling only on the Sleeve Handle and position the Delivery Catheter tip inside the Clip Introducer. Begin gently aspirating the Guide (starting when the CDS is approximately halfway into the Guide, approximately 40 cm retracted) using a 50-60 cc syringe.
- 14.1.1.8 Remove the CDS and the Clip Introducer simultaneously from the Guide by pulling on the Sleeve shaft and Clip Introducer. Ensure the Delivery Catheter tip is inside the Clip Introducer by visualizing the Proximal Sleeve alignment marker just outside the Clip Introducer. Aspirate the Guide during removal of the CDS and Clip Introducer. Cover Guide Hemostasis Valve with finger upon CDS removal. If necessary, position the Guide Handle below the level of the LA to allow blood to fill the Guide Lumen.
 - WARNING:** DO NOT remove the tip of the CDS from the Guide without removing the Clip Introducer simultaneously. Failure to remove the Clip Introducer simultaneously may result in air embolization and/or user injury.
 - WARNING:** DO NOT create a vacuum while removing the CDS from the Guide; air may enter the lumen of the Guide. Patient injury may result.
- 14.1.1.9 Aspirate using a 50-60 cc syringe to remove any remaining air from the Guide.

14.1.2 Removal of the CDS and Guide simultaneously.

- 14.1.2.1 Release the DC Fastener.
- 14.1.2.2 Slowly release Sleeve curves by rotating the M/L Knob and the A/P Knob to neutral.
- 14.1.2.3 Secure the DC Fastener once Sleeve curves are released.
- 14.1.2.4 Straighten the Guide with the +/- Knob when the Delivery Catheter tip is free from the left atrial wall and the mitral valve.
- 14.1.2.5 Release the Sleeve Fastener and retract the CDS approximately 10 cm into the Guide by pulling only on the Sleeve Handle.
- 14.1.2.6 Carefully retract the Guide tip into the RA. The Guide may be straightened further with the +/- Knob if desired.
- 14.1.2.7 Remove the MitraClip System from the femoral vein, while providing

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 37 of 39	

hemostasis.

14.2 MITRACLIP SYSTEM REMOVAL WITH CLIP ATTACHED

14.2.1 Removal of the CDS while leaving the Guide in place.

14.2.1.1 Confirm Clip is locked.

14.2.1.2 *Fully Close the Clip Arms.*

WARNING: Failure to *Fully Close the Clip Arms* prior to retraction into the Guide may result in device damage, inability to remove the CDS and/or patient injury.

14.2.1.3 *Lower the Grippers.*

14.2.1.4 Release the DC Fastener and retract the DC Handle until the DC Radiopaque Ring is fully against the tip of the Sleeve.

14.2.1.5 Slowly release Sleeve deflection by rotating the M/L Knob and the A/P Knob to neutral.

14.2.1.6 Secure the DC Fastener once Sleeve curves are released.

14.2.1.7 Straighten the Guide with the +/- Knob when the tip of the MitraClip Device is free from the left atrial wall and the mitral valve.

WARNING: Failure to straighten the Guide prior to retracting the Clip into the Guide may result in device damage, inability to remove the CDS and/or patient injury.

14.2.1.8 Release the Sleeve Fastener and retract the CDS into the Guide by pulling only on the Sleeve Handle.

NOTE: If resistance is noted, advance and rotate the Clip by rotating the DC Handle then retract the CDS into the Guide. The Guide and/or Sleeve position may also be adjusted to facilitate Clip entry into the Guide. If necessary, retract the Sleeve or advance the Clip to create a 2-3cm separation to facilitate Clip entry into the Guide.

WARNING: Failure to utilize fluoroscopic guidance while retracting the CDS into the Guide may result in device damage, inability to remove the CDS and/or patient injury.

14.2.1.9 Confirm that the Clip Introducer is still fully advanced in the Guide Hemostasis Valve.

14.2.1.10 Retract the CDS by pulling only on the Sleeve Handle and position the Clip inside the Clip Introducer. Begin gently aspirating the Guide (starting when the CDS is approximately halfway into the Guide, approximately 40 cm retracted) using a 50-60 cc syringe.

14.2.1.11 Remove CDS and Clip Introducer simultaneously from the Guide by pulling on the Sleeve shaft and Clip Introducer. Ensure the Clip is inside the Clip Introducer by visualizing the Proximal Sleeve alignment marker just outside the Clip Introducer. Aspirate the Guide during removal of the CDS and Clip Introducer. If necessary, position the Guide Handle below the level of the LA to allow blood to fill the Guide lumen.

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 38 of 39	

WARNING: DO NOT remove the tip of the CDS from the Guide without removing the Clip Introducer simultaneously and with the Clip inside the Clip Introducer. Failure to remove the Clip Introducer simultaneously may result in air embolization.

WARNING: DO NOT create a vacuum while removing the CDS from the Guide; air may enter the lumen of the Guide. Patient injury may result.

WARNING: DO NOT re-use the CDS after removal. Replace the CDS with a new device. Reinserting the CDS after removal may result in inability to open the Clip. Patient injury may result.

14.2.1.12 Aspirate using a 50-60 cc syringe to remove any remaining air from the Guide.

14.2.2 Simultaneous removal of CDS and Guide.

14.2.2.1 Confirm Clip is locked.

14.2.2.2 *Fully Close the Clip Arms.*

WARNING: Failure to *Fully Close the Clip Arms* prior to retraction into the Guide may result in device damage, inability to remove the CDS and/or patient injury.

14.2.2.3 *Lower the Grippers.*

14.2.2.4 Release the DC Fastener and retract the DC Handle until the DC Radiopaque Ring is fully against the tip of the Sleeve.

14.2.2.5 Slowly release Sleeve deflection by rotating the M/L Knob and the A/P Knob to neutral.

14.2.2.6 Secure the DC Fastener once Sleeve curves are released.

14.2.2.7 Straighten the Guide with the +/- Knob when the tip of the MitraClip Device is free from the left atrial wall and the mitral valve.

WARNING: Failure to straighten the Guide prior to retracting the Clip into the Guide may result in device damage, inability to remove the CDS and/or patient injury.

14.2.2.8 Release the Sleeve Fastener and retract the CDS approximately 10 cm into the Guide by pulling only on the Sleeve Handle.

NOTE: If resistance is noted, advance and rotate the Clip by rotating the DC Handle then retract the CDS into the Guide. The Guide and/or Sleeve position may also be adjusted to facilitate Clip entry into the Guide. If necessary, retract the Sleeve or advance the Clip to create a 2-3cm separation to facilitate Clip entry into the Guide.

WARNING: Failure to utilize fluoroscopic guidance while retracting the CDS into the Guide may result in device damage, inability to remove the CDS and/or patient injury.

14.2.2.9 Carefully retract the Guide tip into the RA. The Guide may be straightened further with the +/- Knob if desired.

14.2.2.10 Remove the MitraClip System from the femoral vein, while providing

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.

	MitraClip Clip Delivery System IFU United States	Document: IFUXXXXXXX	Rev.: X
		Page: 39 of 39	



hemostasis.

PATENTS

This device and its use are covered by one or more of the following US patents: 7,736,388; 7,682,369; 7,666,204; 7,655,015; 7,608,091; 7,604,646; 7,563,267; 7,464,712; 7,288,097; 7,226,467; 7,048,754; 6,770,083; 6,752,813; 6,660,083; 6,629,534; 6,461,366; 6,269,819. Additional US and Foreign patents pending.

© 2012, Evalve, Inc. All rights reserved.
MitraClip is a trademark of the Abbott Group of Companies.

NON-HARMONIZED SYMBOLS USED FOR LABELING

	Caution: Contents are STERILE in unopened and undamaged packaging. Parts of the device that are in either direct or indirect contact with circulating blood are NON-PYROGENIC.
	MR Conditional



Manufacturer:
Evalve, Inc.
4045 Campbell Ave.
Menlo Park, CA 94025 USA
tel: 650-833-1600 / fax: 650-330-8114
<http://www.mitraclip.com>

CONFIDENTIAL

May not be reproduced outside of Abbott Vascular without written permission from Document Control.